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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,487	03/15/2004	James McSwiggen	04-218 (400.148)	9362

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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	**PAPER NUMBER**
1635	

MAIL DATE	DELIVERY MODE
10/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,487	MCSWIGGEN, JAMES	
	Examiner	Art Unit	
	Louis V. Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,13-21 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 3, 13-21, and 30-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/28/07 has been entered.

Status of Application/Amendment/Claims

Applicant's response, filed 8/28/2007, to the Final Office Action, mailed 6/5/2007, is acknowledged.

Also acknowledged are Applicants' amendments to the claims. With entry of the amendment filed on 8/28/2007, claims 1, 3, 13-21, and 30-34 are pending and subject to restriction as explained below. The amendment adds new claims 32-34.

Election/Restrictions

Applicants' amendments to the claims necessitates the following restriction requirement.

With entry of the amendments submitted 8/28/2007, the application is now drawn to a multitude of independent or distinct nucleic acid molecules.

> 37 CFR 1.142(a), second sentence, indicates that a restriction requirement "will normally be made before any action upon the merits; however, it may be made at any time before final action. This means the examiner should make a proper requirement as early as possible in the prosecution, in the first action if possible, otherwise, as soon as the need for a proper requirement develops. Before making

> a restriction requirement after the first action on the merits, the examiner will consider whether there will be a serious burden if restriction is not required. MPEP 811.
>
> Since 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. *Ex parte Benke*, 1904 C.D. 63, 108 O.G. 1588 (Comm'r Pat. 1904). MPEP 811.02.

With entry of the instant amendment a serious burden has become apparent.

In the instant case, Applicants' amendments to the claims, particularly independent claim 1, now require the Examiner to consider not only the type of modification present in the claimed nucleic acid, but also the degree, or percentage, of nucleotides containing that modification. Adding to the complexity of the instant claims is the fact that Applicant's amendments require a consideration of several different alternative embodiments of the claimed nucleic acid, which may differ in the first instance by the type and percentage of 2'-sugar, terminal, and internucleotide linkage modifications, recited as a Markush group in claim 1, part e; in the second instance by the type, placement, and number of modified purine and/or pyrimidine units that must be present in the sense and/or antisense strands (claim 1, part f, and claims 13-21 and 32); in the third instance by the placement of a terminal cap moiety; and in the fourth instance by the length of and type of modification present in the 3' overhang(s) (new claims 33 and 34).

For example, Applicants' amendments to claims 13-21 and 32 now require the examiner to consider not only the limitation "one or more" but 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more" in relation to the number of pyrimidine and purine residues in the molecule of

claim 1 that must be modified. Claim 16 requires the Examiner to evaluate nucleic acids of claim 1 having specifically located terminal cap moieties, at either or both ends of the sense strand. New claims 33 and 34 now require the examiner to consider a myriad of different molecules having different lengths of 3' overhang, which may further comprise one or more chemical modifications.

Altogether, then, the claims as now amended require the Examiner to search and examine a multitude of molecules having a variety of different combinations of modifications in the sense strand, the antisense strand, or both. Countless numbers of combinations and configurations are specifically claimed, imposing a serious burden on the examiner.

It is clear, therefore, that with continuing prosecution of the instant application, the claims have become increasingly more complex, drawn now to several different structurally and functionally distinct inventions, deviating significantly in form and function from that originally claimed, imposing a serious burden on the examiner.

It is further clear from the prosecution history to date that applicant's position is that the patentability of the claimed invention depends in part or in full not only on the type of modification but on the particular constellation of modifications present in the nucleic acid.

Thus, the application now specifically claims a multitude of related but distinct products, that differ one from the other both structurally and functionally.

The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or

effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In the instant case the inventions as claimed have materially different designs. For example, with regard to claim 1, parts e and f, nucleic acid molecules that comprise from about 50 to 100% 2'-fluoro modifications are structurally distinct from those that comprise from about 50 to 100% 2'-O-methyl modifications. Similarly, a molecule 100% modified with deoxyabasic modifications is structurally distinct from one that is 100% modified with phosphorothioate modifications. For the same reasons the inventions do not overlap in scope, and there is nothing of record to indicate the nucleic acids to be obvious variants of one another.

Searching and examining each of these molecules would present an undue burden on the Examiner given that each molecule would require a different keyword search and consideration of the patent and non-patent literature with regard to novelty, obviousness, written description, and enablement.

Therefore, Applicant is required under 35 U.S.C. 121 to elect a single disclosed invention for prosecution on the merits to which the claims shall be restricted if no generic linking claim is finally held to be allowable.

Thus, Applicant must elect a single structurally distinct molecule for prosecution on the merits. Applicant is advised that this is not a species election but an election of a single independent or distinct invention.

With regard to claim 1, part e, applicant must elect a single modification for each of the sense and antisense strands.

With regard to claim 1, part f, applicant must elect "one" or "both" strands with respect to each modification recited therein, as the limitation describes different molecules having distinct characteristics.

With regard to claims 13-15, 18-20, and 32-34, Applicant must elect a defined number of modified nucleotides and a defined overhang length. Should Applicant elect a number less than "10...or more", Applicant will receive an examination of that embodiment with consideration towards other embodiments recited therein which fall within the scope of that embodiment. For example, should applicant elect 5 or more, and should 5 or more be found allowable, the recited embodiments "6, 7, 8, 9, and 10 or more" will be considered for rejoinder. However, to be responsive, applicant must elect a specific value. Moreover, Applicant is notified that "5 or more" is distinct from "5."

With regard to claim 16, applicant must elect a single position of the terminal cap moiety.

To be fully responsive to this requirement Applicant's election must designate a single, structurally distinct molecule from claim 1, wherein the features of such molecule are not mutually exclusive, nor should the features define alternatives for prosecution on the merits. Applicant must then further elect a single structurally distinct molecule thereof from each of the claims dependent on claim 1. Altogether, the elections should not include molecules having mutually exclusive features nor more than one alternative in any claim or group of claims, since alternatives would defined molecules having materially different designs. See for example claim 16.

Limitations such as "one or both strands" (e.g., as found in claim 1 among others) are considered to represent alternatives and do not define a single molecule. Applicant must elect

"one" or "both" as it applies to any modification recited therein to be responsive to this requirement.

Applicant is advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the election of single molecule from claim 1, linking claim practice will be in effect with regard to that embodiment.

Upon the indication of allowability of a linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

/Louis Wollenberger/
Examiner
USPTO, Art Unit 1635
October 18, 2007